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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,856

Applicant(s)

ZHANG ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/03; 6/23/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Office Action of 9/22/05 is vacated and this is a Supplemental Action.

Receipt of the Information Disclosure Statement filed on 10/20/03 and 6/23/03 is acknowledged.

Claims 1-6 are pending in this application.

Priority

Priority to US provisional 60/455332 filed 3/17/03 is acknowledged.

Information Disclosure Statement

The information disclosure statement filed 6/23/03 has been considered. The documents in Information Disclosure Statement of 10/20/03 have been considered except for EP 1262166 because it fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. It should be noted that the abstract applicant has submitted is not the abstract of EP 1262166, rather it is an abstract of EP 1272166.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract.

Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid . The dicarboxylic acid salt (C) include alkali metal (for example, **sodium**, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; alkanolamine (for example, **triethanolamine**) salts; basic amino acid (for example, lysine, arginine) salts and ammonium salts. These dicarboxylic acid salt may be added in the form of a salt at the step of the preparation of the skin cosmetic of the present invention. Alternatively, an acid may be added followed by the addition of an alkali (sodium hydroxide, etc.) to thereby form the aimed salt via *neutralization* in the system. To achieve a sufficient moisturizing effect while avoiding excessive irritation, it is preferable that the total content of these components (B) and (C), in terms of the acid, in the skin cosmetic of the present invention falls within a range of from 0.01 to 20% by

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weight, still preferably from 0.05 to 15% by weight and still preferably 0.01 to 10% by weight.

To achieve a sufficient moisturizing effect while avoiding irritation due to the acid, it is preferable that the molar ratio of the components (B) to (C) falls within a range of from 1/9 to 9/1, still preferably from 2/8 to 8/2. See column 3, lines 30-60. Furthermore, Jokura teaches regulating the pH value of the skin cosmetic, which contains the components (B) and (C), to pH 3 to 10, still preferably to pH 3 to 9, to avoid the irritation observed at a pH value less than 3 or exceeding 10. see column 3, lines 60-65.

When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

Specifically, example 3 teaches a sunscreen lotion comprising an organic acid, 0.5% of an organic acid salt (specifically sodium fumarate), and 2% 4,4-t-butyl-methoxybenzoylmethane (component ii with the instant UV range), among other components.

Jokura et al do not exemplify the instant malonic acid salt among the various dicarboxylic acid salts disclosed. Further, Jokura does not specify the acid to salt molar ratio.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Jokura et al and utilize the instant malonic acid salt in the sunscreen lotion of example 3 of Jokura. One would have been motivated to utilize the instant malonic acid salt versus the exemplified sodium fumarate (fumaric acid salt) of example 3 with a reasonable expectation of success since Jokura teaches **malonic acid**, succinic acid, **fumaric acid**, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic

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acid are *all* suitable dicarboxylic acid for the composition. Therefore, the selection of the instant acid salt is considered *prima facie* obvious since the prior art teaches that the criticality of selecting the acid is that it is a dicarboxylic acid and not the selection of the specific dicarboxylic acid itself.

Regarding claims 2-3, although Jokura does not specify the molar ratio of acid: salt, it would have been obvious to a skilled artisan to manipulate this ratio. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent), adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Jokura teaches the importance of avoiding skin irritation due to the acid; thus the pH must be above 3 and below 10 (see column 3, lines 30-65). Therefore, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render a pH that does not irritant the skin wherein using equimolar amounts of the salt and acid (full neutralization) would increase the pH whereas partial neutralization of the acid would decrease the pH since the compound is in an acidic form. Additionally, it should be noted that generally differences in concentrations do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 1-4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 61215318 to Sadashige (entire document).

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Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm and hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6.

Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid salt by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

Sadashige does not exemplify the instant malonic acid salt among the dicarboxylic acid salts disclosed. Further, Sadashige does not specify the acid to salt molar ratio.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Sadashige and utilize the instant malonic acid salt. Firstly, Sadashige teaches that the organic acid **and/or** its salt may be utilized wherein the examples teach the use of the organic acid salt by itself or in combination with organic acid. Secondly, Sadashige teaches that malonic acid is a suitable organic acid to utilize in

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the invention. Therefore, a skilled artisan would have been motivated to utilize the instantly claimed malonic acid salt with a reasonable expectation of success since Sadashige clearly suggests the use of malonic acid and/or its salt as one of the organic acids of choice. Moreover, the selection of a particular acid is considered *prima facie* obvious since the prior art teaches that the criticality of selecting the acid is that it must be an organic acid and not the selection of the specific organic acid itself.

Regarding claims 2-3, although Sadashige does not specify the molar ratio of acid: salt, it would have been obvious to a skilled artisan to manipulate this ratio. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt, adjusts the pH of the composition. Therefore, one would have been motivated to utilize the desired ratio of salt to acid depending on the desired pH of the composition wherein using equimolar amounts of the salt and acid (full neutralization) would increase the pH whereas partial neutralization of the acid would decrease the pH since the compound is in an acidic form. Additionally, it should be noted that generally differences in concentrations do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/347982 in view of JP 61215318 to Sadashige (entire document).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Co-pending application '982 independent claims 1 and 6 are directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a mono-hydroxy substituted amine salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claims 2 and 7 are specifically directed to a dimethylaminoethanol. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 5 is directed to a pH of 4-7.

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 5 is specifies dimethylaminoethanol in a Markush group as

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the salt. Dependent claim 2 is directed to the molar ration of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200.

The co-pending application does not claim the instant organic sunscreen, component (ii).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and utilize an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm in the composition of co-pending application '982 and arrive at instantly claimed invention. One would have been motivated to do

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so since Sadashige teaches the combination of the instant organic sunscreen and an organic acid salt such as malonic acid salt, wherein the organic sunscreen provides UV protection while the malonic acid salt reduces discoloration of the product. Therefore, a skilled artisan would have been motivated to add a sunscreen to the cosmetic composition of '982 to render a cosmetic sunscreen composition. A skilled artisan would have expected success since both the instant application and copending application are directed to cosmetic compositions and copending application has comprising language which allows for the inclusion of additional cosmetically effective agents such as instant organic sunscreen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/601731 in view of JP 61215318 to Sadashige (entire document).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Co-pending application '731 independent claims 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test. Dependent claim 3 is directed to the molar ration of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a

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cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to amine salts.

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to the same amine salts recited in copending '731.

The co-pending application does not claim the instant organic sunscreen, component (ii).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or

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salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and utilize an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm in the composition of co-pending application '731 and arrive at instantly claimed invention. One would have been motivated to do so since Sadashige teaches the combination of the instant organic sunscreen and an organic acid salt such as malonic acid salt, wherein the organic sunscreen provides UV protection while the malonic acid salt reduces discoloration of the product. Therefore, a skilled artisan would have been motivated to add a sunscreen to the cosmetic composition of '982 to render a cosmetic sunscreen composition. A skilled artisan would have expected success since both the instant application and copending application are directed to cosmetic compositions and copending application has comprising language which allows for the inclusion of additional cosmetically effective agents such as instant organic sunscreen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 7 of copending Application No. 10/601819 in view of JP 61215318 to Sadashige (entire document).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Co-pending application '819 independent claims 1 is directed to a cosmetic composition comprising: (i) a first amine present as a neutralized counterion salt of a C2-C4c carboxylic acid other than an alpha- or beta-hydroxycarboxylic acid; (ii) a second amine different from the first amine and having a molecular weight no lower than about 100; (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to malonic acid. Dependent claim 7 is specifically directed to dimethylaminoethanol as the first amine (the amine salt of the carboxylic acid).

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 5 is specifies dimethylaminoethanol in a Markush group as the salt. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200.

The co-pending application does not claim the instant organic sunscreen, component (ii).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid,

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butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and utilize an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm in the composition of co-pending application '731 and arrive at instantly claimed invention. One would have been motivated to do so since Sadashige teaches the combination of the instant organic sunscreen and an organic acid salt such as malonic acid salt, wherein the organic sunscreen provides UV protection while the malonic acid salt reduces discoloration of the product. Therefore, a skilled artisan would have been motivated to add a sunscreen to the cosmetic composition of '982 to render a cosmetic sunscreen composition. A skilled artisan would have expected success since both the instant application and copending application are directed to cosmetic compositions and copending application has comprising language which allows for the inclusion of additional cosmetically effective agents such as instant organic sunscreen. Additionally, the manipulation of the molar

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ratio of acid: salt is considered to be an obvious modification to those skilled in the art. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid adjusts the pH of the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/374300 in view of JP 61215318 to Sadashige (entire document).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Co-pending application '300 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of salt which is an amine neutralized malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier, wherein the composition has a pH ranging from about 1.8-6.5. Dependent claim 2 is specifically directed to ammonia as the amine. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 5 is directed to a pH of 3-5.5.

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically

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acceptable carrier. Dependent claim 2 is directed to the molar ration of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to same amine salts.

The co-pending application does not claim the instant organic sunscreen, component (ii).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and utilize an organic sunscreen agent having a chromophoric group

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active within the ultraviolet radiation range of 280 to 400 nm in the composition of co-pending application '300 and arrive at instantly claimed invention. One would have been motivated to do so since Sadashige teaches the combination of the instant organic sunscreen and an organic acid salt such as malonic acid salt, wherein the organic sunscreen provides UV protection while the malonic acid salt reduces discoloration of the product. Therefore, a skilled artisan would have been motivated to add a sunscreen to the cosmetic composition of '982 to render a cosmetic sunscreen composition. A skilled artisan would have expected success since both the instant application and copending application are directed to cosmetic compositions and copending application has comprising language which allows for the inclusion of additional cosmetically effective agents such as instant organic sunscreen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/767679 in view of JP 61215318 to Sadashige (entire document).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Co-pending application '679 independent claim 1 is directed to a cosmetic composition comprising: (i) 0.001-10% of a fragrance comprising a terpenoid, (ii) from about 0.0001 to about 30% by weight of salt which is an amine neutralized malonic acid; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully

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neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium (an amine) and combinations. Dependent claim 5 is directed to amine salts.

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ration of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to same amine salts as in '679.

The co-pending application does not claim the instant organic sunscreen, component (ii).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in

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dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and utilize an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm in the composition of co-pending application '679. One would have been motivated to do so since Sadashige teaches the combination of the instant organic sunscreen and an organic acid salt such as malonic acid salt, wherein the organic sunscreen provides UV protection while the malonic acid salt reduces discoloration of the product. Therefore, a skilled artisan would have been motivated to add a sunscreen to the cosmetic composition of '982 to render a cosmetic sunscreen composition. A skilled artisan would have expected success since both the instant application and copending application are directed to cosmetic compositions and copending application has comprising language which allows for the inclusion of additional cosmetically effective agents such as instant organic sunscreen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1, 4, and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of U.S. Patent No. 5,961,961 in view of JP 61215318 to Sadashige (entire document).

US '961 claim A sunscreen cosmetic composition comprising: (i) from about 0.01 to about 5% by weight of an oil dispersible inorganic sunscreen particulate having an average particle size of from about 0.1 to about 20 micron; (ii) from about 0.1 to about 5% by weight of an organic sunscreen agent with a chromophoric group active within the ultraviolet radiation range from 290 to 400 nm; (iii) from about 0.5 to about 50% by weight of an emollient oil; and (iv) from about 1 to about 90% by weight of water. Dependent claim 2 is directed to the organic sunscreen agent is selected from the group consisting of benzophenone-3, benzophenone-4, benzophenone-6, benzophenone-8, benzophenone-12, **butyl methoxy dibenzoyl methane**, PABA, octyl dimethyl PABA, octyl methoxycinnamate and combinations thereof. 7. Dependent claim 7 is directed to the composition having a pH ranging from about 5 to about 7.5.

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium,

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sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to same amine salts.

The co-pending application does not claim the instant malonic acid salt component (i).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate. Sadashige teaches the sole use of the organic sunscreen results in discoloration of the product over time. This product discoloration is reduced with the addition of a organic acid and/or its salt. See page 1 of translation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and add the instant malonic acid salt to the composition of US '961 to prevent discoloration of the cosmetic product, which occurs with the sole use of 4-(1,1-

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dimethylethyl)-4-methoxydibenzoylmethane (an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm). Therefore, a skilled artisan would have been motivated to add the instant malonic acid salt in US '123 to provide for a anesthetically pleasing cosmetic sunscreen composition that is stable over time. Lastly, a skilled artisan would have expected success since both the instant application and US '961 are directed to cosmetic compositions and US '961 has comprising language which allows for the inclusion of additional agents such as instant organic acid salt.

Claims 1, 4, and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, and 7 of U.S. Patent No. 6,495,123 in view of JP 61215318 to Sadashige (entire document).

US '123 claims 1 and 7 are directed a cosmetic composition comprising: (i) from about 0.1 to about 15% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range from 290 to 400 nm; (ii) from about 0.01 to about 10% by weight of a water-insoluble powdered polymer formed as porous particles having an Oil Absorbance (castor oil) value ranging from about 90 to about 500 ml/100 gm; and (iii) from about 1 to about 99% of water, the composition having a pH of less than 7. Dependent claim 2 is directed to a composition of claim 1 wherein the sunscreen agent is octyl methoxycinnamate.

Instant application is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the

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malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to same amine salts.

The co-pending application does not claim the instant malonic acid salt component (i).

Sadashige teaches a skin composition reducing skin discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate. Sadashige teaches the sole use of the organic sunscreen results in discoloration of the product over time. This product discoloration is reduced with the addition of a organic acid and/or its salt. See page 1 of translation.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made look to Sadashige and add the instant malonic acid salt to the composition of US '123 to prevent discoloration of the cosmetic product, which occurs with the sole use of 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm). Therefore, a skilled artisan would have been motivated to add the instant malonic acid salt in US '123 to provide for a aesthetically pleasing cosmetic sunscreen composition that is stable over time. Lastly, a skilled artisan would have expected success since both the instant application and US '123 are directed to cosmetic compositions and US '123 has comprising language which allows for the inclusion of additional agents such as instant organic acid salt.

Pertinent Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 01/85129; US 2,586,288; and GB 1,589,224 are made of record.

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

